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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,861	02/15/2005	Bernard Bouffier	BDL-67	3004

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LUCAS & MERCANTI, LLP
475 PARK AVENUE SOUTH
15TH FLOOR
NEW YORK, NY 10016

EXAMINER	
HOPKINS, CHRISTINE D	
ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 12/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/524,861	BOUFFIER, BERNARD	
	Examiner	Art Unit	
	Christine D. Hopkins	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *22 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,18,21-36 and 38-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-18, 21-36 and 38-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed September 22, 2006. Claims 17, 18, 21-36 and 38-40 are now pending. The Examiner acknowledges the amendments to claims 17 and 36, as well as the cancellation of claims 19, 20 and 37.

Claim Objections

2. Claim 36 is objected to because of the following informalities: at line 48, "closure of" should apparently read --closing--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17, 18, 21-36 and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. On page 5 at line 11 of claim 17, it is unclear as to whether or not "the upper part" and "the lower part" of the cage-forming device are the same as "the upper end" and "the lower end" at line 4 of the same page.

5. Claim 36 at line 8 of page 13 recites the limitation "the cage-forming device." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

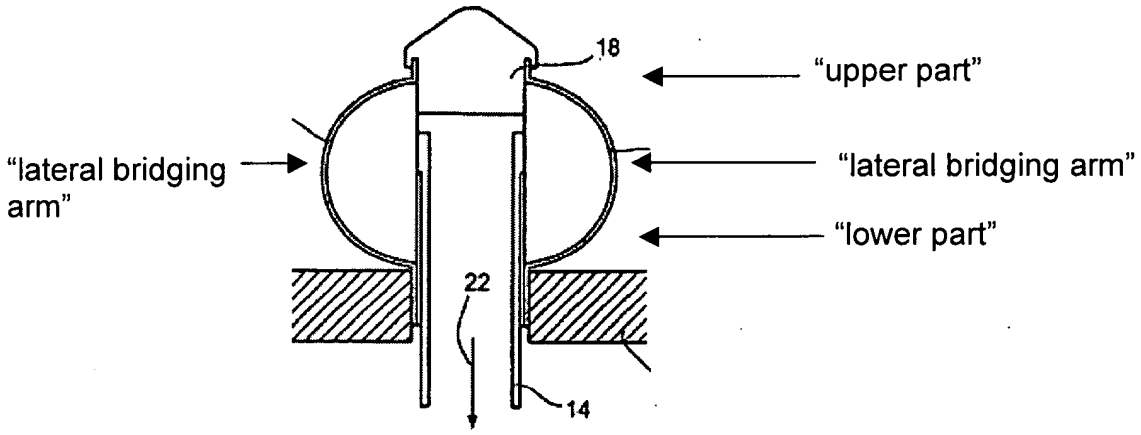
6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 17-18 and 21-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Skiba et al. (U.S. Patent No. 6,908,473). Skiba et al. (hereinafter Skiba) disclose an invention comprising a tissue anchoring device and suspending device used in conjunction with the tissue anchoring device for engaging and supporting an organ. In reference to claims 17 and 34, the invention of Skiba comprises "an elongated component" or suspending device (element 50 of Fig. 5a) that acts as a sling and is flexible so that it may engage a biological vessel or organ (col. 9, lines 25-29). Skiba also teaches an anchoring device comprising a "traction component" (element 24) and connector (element 14 of Fig. 4a), or "sliding component" that work in conjunction to facilitate elastic compliance from a pulling force placed on the bladder by the sling, or "elongated support component". Furthermore, the anchoring device of Skiba assumes the form of a "cage" as presented in Fig. 2b, and is configured to enable pulling on the proximal portion (element 24), or "traction component" for suspending the bladder in the proper position as a result of it's direct force on the sling or "elongated support component" (col. 8, lines 1-31). An "upper" and "lower" part of the cage are joined to

one another by a series of lateral bridging arms (see depiction below), constructed of a flexible and deformable material such that they may assume varying positions during deployment The anchoring device of Skiba is constructed from a biocompatible polymer, or "flexible and deformable material" (col. 7, lines 15-19). A kinking is induced at a midpoint by

pulling on the traction component in a direction indicated by element 22, following insertion into the tissue region (element 20) thus allowing an "umbrella-type" positioning (see transition from Figs. 2a to 2b).



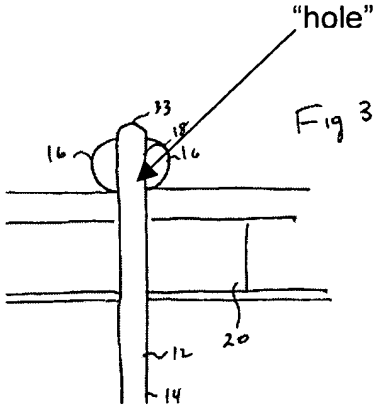
With respect to claim 18, the anchoring device of Skiba may be inserted into a tissue or biological vessel of interest, such as a urethra (col. 10, lines 25-32).

With respect to claim 21, the connector or "sliding component" (element 14) of the anchoring device of Skiba is configured to be subject to considerable pulling forces

resulting from the draw on the bladder by the "elongated support component" or suspending device, element 50 (col. 8, lines 1-13).

With respect to claim 22, the "traction component," or proximal portion (element 24) of the connector (element 14), comprises holes or loops which facilitate connection to, and pulling on the "elongated sling," or suspending device in the invention of Skiba (col. 8, lines 1-8). In reference to claim 23, one anchoring device (element 10) may be employed for supporting both ends of the suspending device as portrayed in Fig. 8 of Skiba. Furthermore, in view of claim 24, the invention of Skiba may additionally include two anchoring devices as presented in Fig. 6.

Regarding claim 25, the anchoring device of Skiba forms a "cage" and contains at its upper end a "tubular component" (element 18 of Fig. 2b) and forms a region for the "sliding component," or connector, which is configured with holes for pulling the traction component (col. 8, lines 1-8). Furthermore, with respect to claim 26, the opposing end of element 33 comprises a "hole" which rests against the tissue of the patient as depicted in Fig. 1 of the instant application.



In view of claims 27 and 28, the lower part of the anchoring device of Skiba (element 32) contains a hole through which a syringe or needle may be passed (col. 7, lines 45-49).

With respect to claims 29-30, the suspending device (element 50), or "elongated support component" of Skiba must engage a biological vessel or urethra necessitating its construction from a flexible strip of material such as the patient's abdominal fascia, a fibrous tissue (col. 9, lines 25-29 and col. 2, lines 36-40). Furthermore, in reference to claims 31-33, the invention of Skiba also may be fabricated from a high molecular weight polyethylene (col. 8, lines 33-38). Moreover, the "traction component" or proximal portion of the connector of Skiba may be constructed from the same material, as stated above for providing support to the suspending device or "elongated sling" (col. 8, lines 1-8 and 33-44).

In view of claim 35, the invention of Skiba incorporates an "introducer instrument" or syringe (element 136) and a "protective sheath" or a "guide" (element 128) for fixating the anchoring device (col. 12, lines 21-32). Also refer to Figs. 7-8.

Allowable Subject Matter

8. Claims 36 and 38-40 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.
The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach a method for providing support to an organ, as claimed by Applicant in claim 36, wherein a "cage-forming device" constructed of "a series of lateral

bridging arms" will induce a "kink" at their mid-point for anchoring, or fixating the device to a surface. Furthermore, while the prior art does teach the application of anesthesia and a surgical incision for inserting a sling-like component having an anchoring system, the prior art does not teach or suggest a method such that a cage-forming device having lateral bridging arms will kink at a mid-point to anchor the system disclosed in claim 36 after insertion into the tissue of a patient.

Response to Arguments

9. Applicant's arguments filed September 22, 2006, with respect to the objection to the drawings have been fully considered and are persuasive. The objection of the drawings has been withdrawn.

10. Applicant's arguments filed September 22, 2006, with respect to the objection to the specification have been fully considered and are persuasive. The objection of the specification has been withdrawn.

11. Applicant's arguments filed September 22, 2006, with respect to the rejection of claims 17-35 under 35 U.S.C. 102(e) citing Skiba et al. ('473) have been fully considered and are not persuasive. Applicant contends that since the cage-forming device of claim 37 has been indicated as having allowable subject matter, it should also be allowable upon incorporation into the apparatus claim 17. However, this argument is

not persuasive. Skiba discloses a cage-forming device of an anchoring system having flexible lateral bridging arms for allowing fixation to a patient's tissue upon deployment of the device, as presented in claim 17. Moreover, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

12. Applicant's arguments filed September 22, 2006, with respect to the rejection of claim 36 under 35 U.S.C. 103(a) over LoVuolo (2002/0143234) in view of Kovac ('235), have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new grounds of rejection is made in view of 35 U.S.C. 112, second paragraph. Claim 36 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

13. Applicant's arguments filed September 22, 2006, with respect to the rejection of claims 38-40 under 35 U.S.C. 103(a) over LuVuolo, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new grounds of rejection is made in view of 35 U.S.C. 112, second paragraph. Claim 36 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735

Christine D Hopkins
Examiner
Art Unit 3735